UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,685	08/30/2000	Peter A. Ward	UM-04594	2029

23535 7590 06/26/2003

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
VANDER VEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	18

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/651,685	Applicant(s) WARD ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

Claims 2 and 4 have been canceled previously.

Claims 1, 3 and 5-7 are currently pending and are the subject of examination in the present Office Action.

Drawings

1. In order to avoid abandonment, the drawing informalities noted in Paper No. 14 mailed on October 21, 2002 must now be corrected. Correction can only be effected in the manner set forth in the above noted paper in the "Attachment for PTO-948" entitled "INFORMATION ON HOW TO EFFECT DRAWING CHANGES."

Response to Arguments

2. Applicant's arguments with respect to claims 1, 3 and 5-7 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,686,100 to Raffin et al (A on form PTO-892).

The claims have been amended to recite treating a human patient for sepsis by administering a composition comprising an antibody to SEQ ID NO: 5, which is a C-terminal truncated fragment of the human C5a complement component. The '100 patent teaches the treatment of human patients with sepsis comprising the administration of antibodies to C5a (see entire specification, column 3, lines 8-26 in particular). While the '100 patent is silent regarding antibodies reactive specifically with SEQ ID NO: 5, silence about a property does not necessarily constitute its absence. The '100 patent teaches the

immunization of animals with the 74 amino acid C5a peptide to generate antibodies, while the present specification discloses immunization with a 20 amino acid truncation of the C5a peptide. Absent evidence that immunization with full-length C5a would not generate antibodies to the truncated form, the antibody preparation obtained by the method of the '100 patent would inherently contain antibodies which bind to SEQ ID NO: 5. Applicant is reminded that the instant claim is drafted in an open format, i.e., "a therapeutic composition comprising an antibody specific for SEQ ID NO: 5" (emphasis added for clarity), meaning that the composition may also contain antibodies which react with other portions of C5a as well. In regard to instant claim 5, the '100 patent teaches the production of polyclonal antibodies to human C5a at column 3, line 50 to column 4, line 20 in particular. In regard to instant claim 6, the '100 patent teaches that monoclonal antibodies to human C5a can be "produced by means well known in the art" at column 3, lines 43-47 in particular. The prior art reference anticipates the claimed invention.

4. Claims 1, 3, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 245 993 (14 on form PTO-1449).

The claims have been amended to recite treating a human patient for sepsis by administering a composition comprising an antibody to SEQ ID NO: 5, which is a C-terminal truncated fragment of the human C5a complement component. The '993 publication teaches the treatment of human patients with sepsis comprising the administration of monoclonal antibodies to C5a (page 3, lines 1-47 and page 5, lines 1-48 in particular). While the '993 publication is silent regarding antibodies reactive specifically with SEQ ID NO: 5, silence about a property does not necessarily constitute its absence. The '993 publication teaches the immunization of animals with the 74 amino acid C5a peptide to generate antibodies, while the present specification discloses immunization with a 20 amino acid truncation of the C5a peptide. Absent evidence that immunization with full-length C5a would not generate antibodies to the truncated form, the antibody preparation obtained by the method of the '993 publication would inherently contain antibodies which bind to SEQ ID NO: 5. Applicant is reminded that the instant claim is drafted in an open format, i.e., "a therapeutic composition comprising an antibody specific for SEQ ID NO: 5" (emphasis added for clarity), meaning that the composition may also contain antibodies which react with other portions of C5a as well. In regard to instant claim 7, the '993 publication teaches that the monoclonal antibodies of that invention are able to bind C5a in the presence of a molar excess of C5 (page 3, lines 36-39, page 9, lines 1-31 and Table II in particular). The prior art reference anticipates the claimed invention.

Information Disclosure Statement

5. Citations 23, 25, 36 and 67 on the form PTO-1449 filed by Applicant on March 27, 2003 have been lined through and have not been considered. Said citations merely consisted of a copied title page and catalog page of the cited textbooks and did not contain any pages of said citations comprising relevant information. If Applicant wishes to have passages from the citations considered, copies of the relevant pages must be submitted along with a new IDS and form PTO-1449 properly identifying them. In regard to citation #14 on said form PTO-1449, the EP application was drafted in German and only the English language claims were considered.

Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014.Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 24, 2003

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
6/26/03